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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/647,458	08/01/2003	Sophie Chen	CSO-0001-P	2036

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EXAMINER
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GRAFFEO, MICHEL

ART UNIT	PAPER NUMBER
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1614

DATE MAILED: 09/08/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/647,458

Applicant(s)

CHEN, SOPHIE

Examiner

Michel Graffeo

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 17 January 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-43 is/are pending in the application.
- 4a) Of the above claim(s) 4,8-17,25,31,37 and 40-43 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-3,5-7,18-24,26-30,32-36,38 and 39 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>31 May 06 (2 sheets)</u><br><u>11 Jun 06 (1 sheet)</u> | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Election/Restrictions***

Applicant's election without traverse of Group I, wogonin in the reply filed on 17 January 2006 is acknowledged.

Claims 4, 8-17, 25, 31, 37 and 40-43 withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected species, there being no allowable generic or linking claim.

### ***Status of Action***

Claims 1-3, 5-7, 18-24, 26-30, 32-36 and 38-39 are examined.

### ***Claim Objections***

Claim 29 is objected to because of the following informalities: claim 29 ends with two periods. Appropriate correction is required.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-3, 5-7, 18-24, 26-30, 32-36 and 38-39 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Particularly,

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it is unclear what active agents and/or how many active agents are required to meet the claim limitations. For example, the phrase in claim 1 "wogonin, the pharmaceutically acceptable esters and salts, and its selectively substituted analogs" read alone and/or with the "or" phrase in the last line of the claim "or a combination comprising one or more of the foregoing phytoestrogens." makes the claim unclear whether the actives such as wogonin plus its derivatives are necessary, just one of wogonin or its derivatives or multiple claimed actives are required.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-3, 5-7, 18-24, 26-30, 32-36 and 38-39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ogasawara et al. Screening of Natural Compounds for Inhibitory Activity on Colon Cancer Cell Migration Biol. Pharm. Bull. 24(6) 720-723 (2001) in view of Yamamoto et al. The potent anti-tumor-promoting agent isoliquiritigenin. Carcinogenesis Vol 12 No. 2 pg 317-323.

Ogasawara et al. teach wogonin as having anti-neoplastic properties (see Table 2 on page 721) as characterized by studies with colon cancer cells (see Title) Ogasawara et al. further teach the IC<sub>50</sub> of wogonin to be 86.9 µg/ml which is calculated to be a ratio of 15.7 to 1 in one ml of water (MW of water is 18 g/mol and the MW of

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wogonin is 284 g/mol giving a 15.7 to 1 ratio) and therefore suggests the efficacy of a composition comprising greater than 0.5 weight percent of wogonin.

Ogasawara et al. do not teach combination therapies or administration of a particular amount of wogonin to a human. Yamamoto et al. teach that isoliquiritigenin is a potent anti-tumor-promoting agent (see Title). Ogasawara et al. teach various known chemotherapeutics such as cisplatin (see Materials and Methods on page 720) and other natural compounds as anti-cancer agents such as ginsenoside (see Table 1 on page 721). Since combining agents which are known to be useful as chemotherapeutics individually into a single composition useful for the very same purpose is prima facie obvious. See *In re Kerkhoven* 205 USPQ 1069. Since it is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose, the idea of combining isoliquiritigenin, cisplatin and ginsenoside flows logically from their having been individually taught in the prior art. Therefore, a composition comprising wogonin and an anti-cancer agent is prima facie obvious.

Ogasawara et al. additionally suggests the applicability of the agents to human patients wherein it is stated that "Tumor metastasis is a major cause of death in cancer patients, and its blockade has been considered to enable cancer patients to survive (see first paragraph on page 720). Yamamoto et al. also suggest efficacy in humans on page 322, col 2: "and suggest that these compounds show promise as drugs to prevent tumor promotion.". To that extent, a physician would be motivated to optimize and vary the dosage amount depending upon a patient's needs and sensitivities.

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One of ordinary skill in the art would have been motivated to combine the above references and as combined teach the claimed invention as claimed. One of ordinary skill in the art would have been motivated to combine the references because both are directed to the treatment of cancer and Yamamoto et al. is primarily being cited to show the status and knowledge in the art at the time the instant Application was filed. To that extent, isoliquiritigenin is taught to be efficacious as a cancer therapy as well as wogonin. Thus, the combined references teach and make prima facie obvious how to use the claimed invention at the time that it was made.

### ***Conclusion***

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michel Graffeo whose telephone number is 571-272-8505. The examiner can normally be reached on 9am to 5:30pm Monday to Friday.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached on 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

5 September 2006

MG

 9/5/06  
**ARDIN H. MARSCHEL**  
**SUPERVISORY PATENT EXAMINER**